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San Francisco CA 94111-3834

Re: Patent Term Extension
Application for
U.S. Patent No. 5,275,813

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,275,813, which claims the veterinary biologic product product Fel-O-Vax® FIV vaccine and a method of its use, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

The period of extension has been calculated using the United States Department of Agriculture (USDA) determination of the length of the regulatory review period published in the Federal Register of May 8, 2003 (68 Fed. Reg. 24705-06). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,442 - 861) + 1,411 \\ &= 2,202 \text{ days}\end{aligned}$$

Since the regulatory review period began August 28, 1991, before the patent issue date (January 4, 1994), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 28, 1991 to and including January 4, 1994 is 861 days; this period is subtracted from the number of days occurring in the testing phase according to the USDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment (November 16, 1988) of the Generic Animal Drug and Patent Term Restoration Act (35 U.S.C. § 156, as amended to provide for animal drugs and veterinary biological products), see 35 U.S.C. 156(f)(8). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,275,813

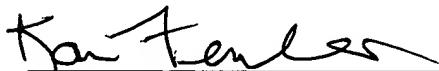
Granted: January 4, 1994
Original Expiration Date¹: January 4, 2011
Applicant: Janet K. Yamamoto
Owner of Record: The Regents of the University of California
Title: Methods and Compositions for Vaccinating Against Feline Immunodeficiency Virus
Product Trade Name: Fel-O-Vax® FIV vaccine
Term Extended: Five years
Expiration Date of Extension: January 4, 2016

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7744

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.



Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Richard E. Hill, Jr.
Center for Veterinary Biologics
510 South 17th Street
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Ames IA 50010 Office of Regulatory Policy

RE: Fel-O-Vax® FIV

¹Subject to the provisions of 35 U.S.C. § 41(b).